_**UCO7.Rec**id PCT/PTO.. US DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

FORM PTO-1399 (REV 11-98) TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

146.1381

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

CONCERNING A FILING UNDER 35 U.S.C. 371 INTERNATIONAL APPLICATION NO INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED PCT/FR00/02393 August 28. August 26, 1999 TITLE OF INVENTION SPHERICAL AGGLOMERATES OF TELITHROMYCIN, THEIR PREPARATION PROC AND THEIR USE IN THE PREPARATION OF PHARMACEUTICAL FORMS APPLICANT(S) FOR DO/EO/US GODARD et al Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information 1. X This is a FIRST submission of items concerning a filing under 35 U.S.C 371. This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U S C 371 This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1). A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date 5. X A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is transmitted herewith (required only if not transmitted by the International Bureau). has been transmitted by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). 6. X A translation of the International Application into English (35 U.S.C. 371(c)(2)). Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are transmitted herewith (required only if not transmitted by the International Bureau). have been transmitted by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. A translation of the amendments to the claims under PCT Article 19 (35 U S C. 371(c)(3)). An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). Unexecuted A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S C. 371(c)(5)) Items 11. to 16. below concern document(s) or information included: 11. X An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. X A FIRST preliminary amendment. A SECOND or SUBSEQUENT preliminary amendment. A substitute specification. 15. A change of power of attorney and/or address letter. 16. \mathbf{x} Other items or information: Amended Pages 3, 4, 5, 6 and 7; PCT/IB/306

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Our Ref.: 146.1381

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

GODARD et al

PCT/FR00/02393

Serial No.:

Filed: Concurrently Herewith For: SPHERICAL...PHARMACEUTICAL

FORMS

PCT Date: August 28, 2000

600 Third Avenue New York, NY 10016 February 11, 2002

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents Washington, D.C. 20231

sir:

Please amend this application as follows:

IN THE SPECIFICATION:

Page 1, before line 1, insert

--This application is a 371 of PCT/FR00/02393 filed August 28, 2000.--

IN THE CLAIMS:

Claim 2 (amended) A spherical agglomerate of telithromycin of claim 1, wherein the size of the particles is between 30 and 400 microns.

Claim 3 (amended) A spherical agglomerate of telithromycin of claim 2, wherein the median size of the particles is between 80 and 150 microns.

Claim 4 (amended) A spherical agglomerate of telithromycin of claim 1, wherein the median size of the particles is about 100 microns.

Claim 5 (amended) A process for the preparation of agglomerates of claim 1, comprising preparing a suspension of telithromycin crystals, and coating the crystals with a phase insoluble in telithromycin from which telithromycin progressively crystallizes.

Claim 6 (amended) The process of claim 5, wherein a solution of telithromycin in acetone is used.

Claim 7 (amended) The process of claim 5, wherein the crystallization takes place in an acetone/isopropyl ether mixture.

Claim 8 (amended) The process of claim 5, wherein the crystallization is carried out between -5°C and -15°C.

Cancel claims 9 to 13 and add the following claims.

--14. A spherical agglomerate of claim 1 micro-encapsulated in

at least one polymer.

A method of treating bacterial infections in humans 15. comprising administering to humans in need thereof antibactericidally effective amount of a composition of claim 10. --

REMARKS

The amendment is submitted to refer to the PCT application, to remove multiple dependency from the claims and to conform the claims to the American practice.

> Respectfully submitted, BIERMAN, MUSERLIAN AND LUCAS

Charles A. Muserlian, #19,683 Attorney for Applicant(s) Tel. # (212) 661-8000

CAM:sd

Enclosures: Marked-Up Version of Specification and Claims

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Spherical agglomerates of telithromycin, their preparation process and their use in the preparation of pharmaceutical

--This application is a 371 of PCT/FR00/02393 filed August 28, 2000.-A subject of the present invention is spherical

5 agglomerates of telithromycin, their preparation process and their use in the preparation of pharmaceutical forms.

Telithromycin or 11,12-dideoxy-3-de((2,6-dideoxy-3-C-methyl-3-O-methyl-alpha-L-ribohexopyranosyl)oxy)-6-O-methyl-3-oxo-12,11-(oxycarbonyl((4-(4-(3-pyridinyl)-1H-imidazol-1-yl)butyl)imino))-erythromycin is a product endowed with antibiotic properties of structure: ...

described and claimed in European Patent 680967.

The oral route is a preferred form of administration for this product. Some patients, children in particular, have difficulty in swallowing tablets and capsules and therefore it is desirable to have available other forms of administration such as for example oral suspensions, ready to use or prepared extemporaneously at the time of use.

CONFIRMATION COPY

CLAIMS

- 1) Spherical agglomerates of telithromycin.
- 2) A spherical agglomerates of telithromycin according to claim 1, characterized in that the size of the particles is between 30 and 400 microns.
- 3) A Spherical agglomerates of telithromycin according to which claim 2, characterized in that the median size of the particles is situated between 80 and 150 microns.
- 4) A Spherical agglomerates of telithromycin according to any where; n one of claims 1 to 3, characterized in that the median size about of the particles is situated towards 100 microns.
 - 5) A process for the preparation of agglomerates according to claim 1, comprising preparing any one of claims 1 to 4, characterized in that a suspension
- of telithromycin crystals is prepared, and these crystals are then coated with a phase insoluble in telithromycin which telithromycin progressively crystallizes.
 - 6) The paration process according to claim 5, characterized in that a solution of telithromycin in acetone is used.
- 20 7) Preparation process according to claim 5 or 6, where: n characterized in that the crystallization takes place in an acetone/isopropyl ether mixture.
 - 8) Preparation process according to any one of claims 5 to wherein 2, characterized in that the crystallization is carried out
- 25 between -5° C and -15° C.

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- 9) Spherical agglomerates of telithromycin as obtained by the process according to any one of claims 5 to 8.
- 10) Spherical agglomerates of telithromycin according to claim 9, characterized in that the particle size is comprised between 30 and 400 microns
- 11) Spherical agglomerates of telithromycin according to claim 10, characterized in that the median size of the particles is situated between 80 and 150 microns.

- 12) Spherical agglomerates of telithromycin according to any one of claims 9 to 11, characterized in that the median size of the particles is situated towards 100 microns.
- 13) Use of the spherical agglomerates according to any one of claims 1 to 4 and 9 to 12, characterized in that the spherical agglomerates are surrounded by a layer of polymer in order to obtain the sought galenical form.

JC11 Rec'd PCT/PTO 12 FEB 2002

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Spherical agglomerates of telithromycin, their preparation process and their use in the preparation of pharmaceutical

forms.

A subject of the present invention is spherical agglomerates of telithromycin, their preparation process and their use in the preparation of pharmaceutical forms.

Telithromycin or 11,12-dideoxy-3-de((2,6-dideoxy-3-C-methyl-3-O-methyl-alpha-L-ribohexopyranosyl)oxy)-6-O-methyl-3-oxo-12,11-(oxycarbonyl((4-(4-(3-pyridinyl)-1H-imidazol-1-yl)butyl)imino))-erythromycin is a product endowed with antibiotic properties of structure:

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described and claimed in European Patent 680967.

The oral route is a preferred form of administration for this product. Some patients, children in particular, have difficulty in swallowing tablets and capsules and therefore it is desirable to have available other forms of administration such as for example oral suspensions, ready to use or prepared extemporaneously at the time of use.

CONFIRMATION COPY

Telithromycin is an active ingredient which has an unpleasant taste. Galenical forms must therefore be produced which mask the taste of the product yet preserve a good bioavailability.

The physico-chemical properties of telithromycin are such that they permit micro-encapsulation, i.e the coating of the active ingredient with a polymer or a mixture of polymers.

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The micro-encapsulation can be carried out by spraying a

10 polymer or by interfacial polymerization or by coacervation.

In order to obtain a good micro-encapsulation, spherical

particles of active ingredient must be available, particles

which are neither too small, to prevent them from

agglomerating among themselves, nor too large, in order that

15 the dissolution is not too slow, and the particles must be

spherical so that the covering of the active ingredient by

the polymer is correct and in order to obtain good release

kinetics for the active ingredient.

A subject of the invention is spherical agglomerates of telithromycin.

The spherical agglomerates are obtained as shown below by direct transformation of the crystals into masses of spherical shape.

As regards spherical agglomerates in general, reference may be had to the article by Frederica Guillaume and Anne-Marie Guyot-Hermann in Il Farmaco XLVIII 1993 pages 473 et seq.

The agglomerates of the invention permit a good microencapsulation and a subject of the invention is in particular the use characterized in that the spherical agglomerates are surrounded by a layer of polymer in order to obtain the sought galenical form, for example micro-capsules.

A subject of the invention is spherical agglomerates of telithromycin characterized in that the size of the particles is between 30 and 400 microns.

A quite particular subject of the invention is spherical agglomerates of telithromycin characterized in that the median size of the particles is situated between 80 and 150 microns and in particular spherical agglomerates of telithromycin characterized in that the median size of the particles is situated towards 100 microns, i.e. characterized in that half of the agglomerates are less than 100 microns in size.

A subject of the invention is also a process for the preparation of spherical agglomerates characterized in that a suspension of telithromycin crystals is prepared, and these crystals are then coated with a phase insoluble in telithromycin which progressively crystallizes.

A subject of the invention is in particular a preparation process characterized in that a solution of telithromycin in acetone is used.

A more particular subject of the invention is a preparation process characterized in that the crystallization takes place in an acetone/isopropyl ether mixture.

In a preferred embodiment, the crystallization is carried out between -5 and -15°C . The size of the spherical agglomerates is controlled by adjusting the stirring speed.

Finally a subject of the invention is spherical agglomerates of telithromycin as obtained by the preparation process described above.

The following example illustrates the invention without, 30 however, limiting it.

EXAMPLE:

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a) Preparation of the acetone solution

The following are introduced under nitrogen:

- telithromycin

64 g

- anhydrous pure acetone

128 ml

Stirring is carried out under a slight nitrogen overpressure between 19°C and 21°C and a check is carried out to ensure that the dissolution is total.

If necessary, the quantity of water is added to obtain a 2.9% product, adding:

- demineralized water

 $0.26 \, \text{ml}.$

b) Crystallization

The following are introduced under nitrogen, into a double-casing reactor fitted with a mechanical stirrer, a thermometric probe and a nitrogen inlet:

- isopropyl ether

640 ml

- anhydrous pure acetone

12.8 ml

The temperature is stabilized between 19°C and 21°C.

5% by mass of the acetone solution is introduced, while stirring at $350~\text{rpm}\,.$

Then, while still stirring at 350 rpm, the crystallization is initiated with 0.96 g of micronized telithromycin suspended by sonication in:

isopropyl ether

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3.2 ml

 ${\tt Crystallization}\ \ {\tt develops}\ \ {\tt immediately}\ \ {\tt after}\ \ {\tt initiation}.$

Stirring is carried out for 15 minutes at $20\pm1^{\circ}\text{C}$ then the suspension is cooled down to $-10\pm1^{\circ}\text{C}$ over 30 minutes.

The rest of the acetone solution is introduced: acetone solution of telithromycin 157.2 g

Stirring is carried out for another 1 hour at -10°C.

c) Isolation

Thorough drying and washing by clarifications are 30 carried out twice with, each time:

isopropyl ether

64 ml.

Drying is carried out in an oven at 40°C under vacuum, followed by sieving on a 500 μm grid.

 $50.4~{
m g}$ of spherical agglomerates of telithromycin are obtained.

Granulometry

The size of the particles is determined by laser diffraction using a HELOS SYMPATEC® model granulometer.

The results obtained are the following:
10% of the particles have a diameter of < 77 microns
50% of the particles have a diameter of < 107 microns
90% of the particles have a diameter of < 166 microns.

10 Figure 1 represents agglomerates obtained by operating as shown above, the scale being

1 cm = 150 microns.

Use

The product of the example was used to prepare, by

simple coacervation or by direct spraying of a suitable
polymer, micro-capsules intended for the preparation of oral
suspensions to be prepared extemporaneously.

The prepared suspensions are accepted by children and retain good release kinetics.

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6 **CLAIMS**

- 1) Spherical agglomerates of telithromycin.
- 2) Spherical agglomerates of telithromycin according to claim 1, characterized in that the size of the particles is between 30 and 400 microns.
- 3) Spherical agglomerates of telithromycin according to claim 2, characterized in that the median size of the particles is situated between 80 and 150 microns.
- 10 4) Spherical agglomerates of telithromycin according to any one of claims 1 to 3, characterized in that the median size of the particles is situated towards 100 microns.
 - 5) Process for the preparation of agglomerates according to any one of claims 1 to 4, characterized in that a suspension
- of telithromycin crystals is prepared, and these crystals are then coated with a phase insoluble in telithromycin which progressively crystallizes.
 - 6) Preparation process according to claim 5, characterized in that a solution of telithromycin in acetone is used.
- 20 7) Preparation process according to claim 5 or 6, characterized in that the crystallization takes place in an acetone/isopropyl ether mixture.

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- 8) Preparation process according to any one of claims 5 to 7, characterized in that the crystallization is carried out between -5°C and -15°C .
- 9) Spherical agglomerates of telithromycin as obtained by the process according to any one of claims 5 to 8.
- 10) Spherical agglomerates of telithromycin according to claim 9, characterized in that the particle size is comprised between 30 and 400 microns.
- 11) Spherical agglomerates of telithromycin according to claim 10, characterized in that the median size of the particles is situated between 80 and 150 microns.

- 12) Spherical agglomerates of telithromycin according to any one of claims 9 to 11, characterized in that the median size of the particles is situated towards 100 microns.
- 13) Use of the spherical agglomerates according to any one of claims 1 to 4 and 9 to 12, characterized in that the spherical agglomerates are surrounded by a layer of polymer in order to obtain the sought galenical form.





(12) DEMANDE INTERNATIONALE PUBLIÉE EN VERTU DU TRAITÉ DE COOPÉRATION EN MATIÈRE DE BREVETS (PCT)

(19) Organisation Mondiale de la Propriété Intellectuelle

Bureau international



(43) Date de la publication internationale 1 mars 2001 (01.03.2001)

PCT

(10) Numéro de publication internationale WO 01/14393 A2

(51) Classification internationale des brevets⁷: A61K /

С07Н,

(74) Mandataire: VIEILLEFOSSE, Jean, Claude Aventis Pharma S.A.; Département des Brevets, 102, route de Noisy, F-93235 Romainville Cedex (FR).

(21) Numéro de la demande internationale:

PCT/FR00/02393

(22) Date de dépôt international: 28 août 2000 (28.08.2000)

(25) Langue de dépôt:

français

(26) Langue de publication:

français

(30) Données relatives à la priorité:

99/10810

26 août 1999 (26.08.1999) F

(71) Déposant (pour tous les États désignés sauf US): AVEN-TIS PHARMA S.A. [FR/FR]; 20, avenue Raymond Aron, F-92160 Antony (FR).

(72) Inventeurs; et

(75) Inventeurs/Déposants (pour US seulement): GODARD, Jean-Yves [FR/FR]; 1A, place des Fêtes, F-93340 Le Raincy (FR). ROGNON, Valérie [FR/FR]; 5, rue des Fougères, F-93470 Coubron (FR).

(81) États désignés (national): AE, AG, AL, AU, BA, BB, BG, BR, BZ, CA, CN, CR, CU, CZ, DM, DZ, EE, GD, GE, HR, HU, ID, IL, IN, IS, JP, KP, KR, LC, LK, LR, LT, LV, MA, MG, MK, MN, MX, NO, NZ, PL, RO, SG, SI, SK, TR, TT, UA, US, UZ, VN, YU, ZA.

(84) États désignés (régional): brevet ARIPO (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), brevet eurasien (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), brevet européen (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), brevet OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Publiée:

 Sans rapport de recherche internationale, sera republiée dès réception de ce rapport.

En ce qui concerne les codes à deux lettres et autres abréviations, se référer aux "Notes explicatives relatives aux codes et abréviations" figurant au début de chaque numéro ordinaire de la Gazette du PCT.

(54) Title: SPHERICAL TELITHROMYCIN CLUSTERS, METHOD FOR THE PRODUCTION AND USE THEREOF IN THE PREPARATION OF PHARMACEUTICAL FORMS

(54) Titre: AGGLOMERATS SPHERIQUES DE TELITHROMYCINE, LEUR PROCEDE DE PREPARATION ET LEUR APPLICATION DANS LA PREPARATION DE FORMES PHARMACEUTIQUES

(57) Abstract: The invention relates to spherical telithromycin clusters and to a method for the production thereof characterized in that a telithromycin crystal suspension is prepared, said crystals are coated with a telithromycin insoluble phase which gradually crystallizes. The spherical telithromycin clusters are used in the preparation of micro-capsules.

(57) Abrégé: L'invention a pour objet les agglomérats sphériques de télithromycine. L'invention a pour objet un procédé caractérisé en ce que l'on prépare une suspension de cristaux de télithromycine, puis enrobe ces cristaux d'une phase insoluble en télithromycine qui cristallise progressivement. Les agglomérats sphériques de l'invention trouvent leur application dans la préparation de micro capsules.



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C44		Filing Date	August 28, 20 00	CE			
Declaration OF		Group Art Unit	AP				
Submitted with Initial Filing	Submitted after Initial Filing	Examiner Name	TECLLOS	N 23			
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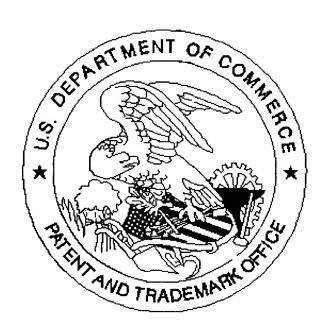


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